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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/764,872 | 01/17/2001 | Craig A. Rosen | PA125 | 6983 |

22195 7590 09/18/2002

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

CHAKRABARTI, ARUN K

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1634

DATE MAILED: 09/18/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,872

Applicant(s)

Rosen, C. , et al.

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7 and 21, drawn to nucleic acids, classified in class 536, subclass 22.1.
 - II. Claims 8-10, drawn to method of making host cells containing a specific nucleic acid, classified in class 536, subclass 25.3.
 - III. Claims 11-14, drawn to polypeptides, classified in class 530, subclass 350.
 - IV. Claims 15-17, drawn to method of making polypeptides, classified in class 530, subclass 333.
 - V. Claims 18-19, drawn to diagnosis of a disease, classified in class 435, subclass 6.
 - VI. Claims 20, 22, and 23, drawn to immunoassay, classified in class 435, subclass 7.1.
 - VII. Claim 24, drawn to treatment of a disease, classified in class 424, subclass 88.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the

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process of making host cells of Group II containing a specific nucleic acid of Group I can be used to make any other host cell containing any nucleic acid, which is materially different product.

3. Inventions of Groups I and III, IV, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of nucleic acids of Group I is not disclosed as capable of use together with polypeptide of Group III, method of making polypeptide of Group IV, immunoassay of Group VI, and treatment of disease of Group VII and they have different modes of operation, different functions, or different effects.

4. Inventions of Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Group I can be used in the diagnosis of a disease by the method of nucleic acid hybridization of Group V or can be used to make RNA and protein or can be used to make antisense nucleic acids for gene therapy.

5. Inventions of Groups II and III-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of method of making of host cells of Group II is not

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disclosed as capable of use together with polypeptide of Group III, method of making polypeptide of Group IV, diagnosis of a disease of Group V, immunoassay of Group VI, and treatment of disease of Group VII and they have different modes of operation, different functions, or different effects .

6. Inventions of Groups III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptide product of Group III can be made by the method of Group IV or can be made by solid phase peptide synthesis using organic chemical reactions.

7. Inventions of Groups III and V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of polypeptide of Group III is not disclosed as capable of use together with diagnosis of a disease of Group V, and treatment of disease of Group VII and they have different modes of operation, different functions, or different effects.

8. Inventions of Groups IV and V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of method of making polypeptide of Group IV is not

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disclosed as capable of use together with diagnosis of a disease of Group V, immunoassay of Group VI, and treatment of disease of Group VII and they have different modes of operation, different functions, or different effects.

9. Inventions of Groups V and VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of diagnosis of a disease of Group V is not disclosed as capable of use together with immunoassay of Group VI, and treatment of disease of Group VII and they have different modes of operation, different functions, or different effects.

10. Inventions of Groups VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of immunoassay of Group VI is not disclosed as capable of use together with treatment of disease of Group VII and they have different modes of operation, different functions, or different effects.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

12. A telephone call was made to Kenley Hoover on September 9, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

Conclusion

14.. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

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Arun Chakrabarti,

Patent Examiner,

September 10, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600